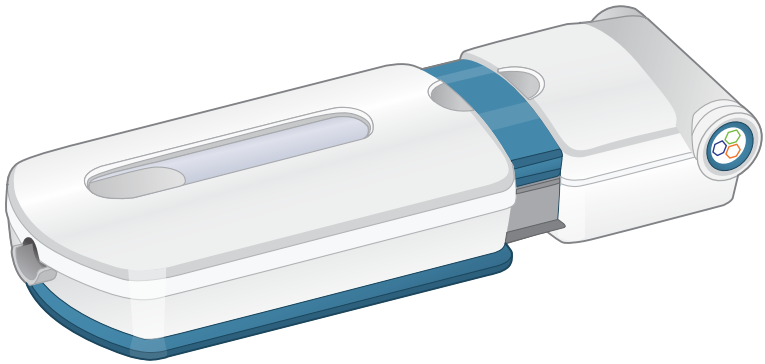
FreedomEdge™
Syringe Infusion System



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Introduction:

The FreedomEdge™ Syringe Infusion System is portable and easy to use, requiring no batteries or electricity. It starts to operate when the pump is closed. RMS Precision Flow Rate Tubing™ sets are used to control the flow rate.

The FreedomEdge™ operates at a constant safe pressure of 13.5psi. The constant pressure developed in the FreedomEdge™ automatically decreases the flow rate if there is an increase in resistance during the delivery. The system will find equilibrium between the increasing resistance and flow rate. It provides constant flow which tends to inhibit clots, and holds full pressure after an infusion is complete to prevent blood or drug backflow. The FreedomEdge™ also eliminates concerns of a bolus, overflow, overdose, or runaway infusion.

The FreedomEdge™ offers all the performance and technology of the FREEDOM60®, in a design for 20ml and 30ml syringes. The FREEDOM60® is designed for 60ml syringes.

Indications for Use:

The FreedomEdge™ Syringe Infusion System is indicated for the infusion of prescribed liquid medicines.

Contraindications:

The FreedomEdge™ is not intended for the delivery of blood, critical* or life-sustaining medications, or for the infusion of insulin.

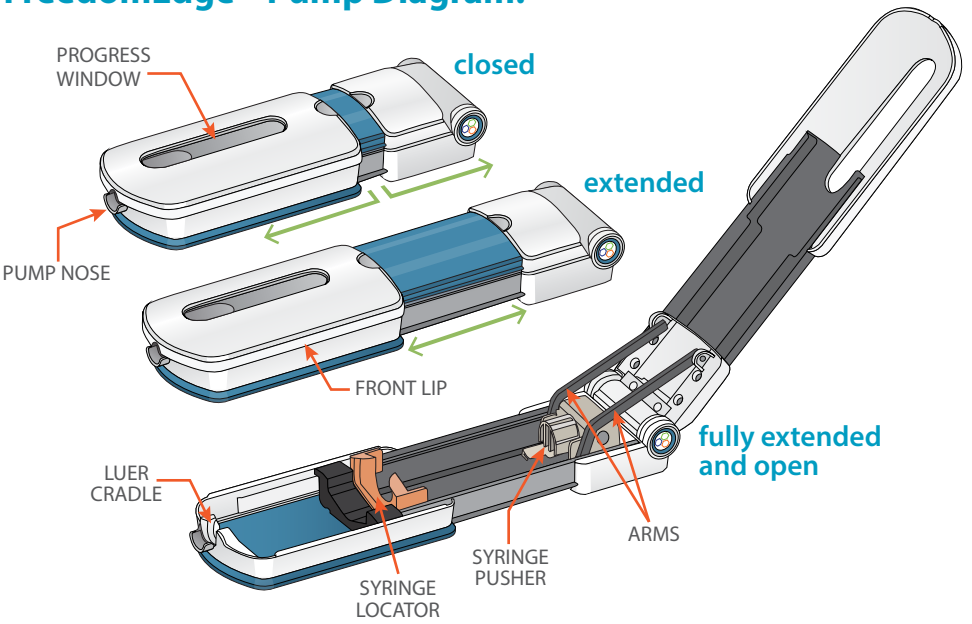
*Critical may be defined as medication requiring greater accuracy of delivery, such as CNS opiate depressants which in certain countries, e.g. UK, may be limited by local regulations. CONSULT LOCAL REGULATORY AUTHORITIES.

Caution:

- Use the FreedomEdge™ Syringe Infusion System only for the patient for whom the device is prescribed and only for its intended use.
- Do not connect an extension tubing or needle set directly to the syringe. An appropriate flow restrictive tubing with a disc luer is required for use with the FreedomEdge™.
- Use only recommended syringes with the FreedomEdge™.
- Do not use syringes smaller than 20ml. The use of a smaller syringe may cause high pressures that can be unsafe for the patient.
- Using the same tubing set, 30ml syringes will have different flow rates and delivery times versus 20ml syringes.
- Before use, carefully inspect the tubing set package. Do not use the tubing set if the package is opened or damaged.
- Do not re-sterilize tubing sets.
- Overuse of the slide clamp or storing tubing sets with the slide clamp engaged for long periods of time* may damage the tubing and affect the infusion rate.
- Carefully inspect the FreedomEdge™ Syringe Infusion Pump before use. Verify its condition and test. If the pump is believed to not be operating properly or at the appropriate rate of flow, immediately discontinue use.
- The FreedomEdge™ Syringe Infusion System does not have an alarm, therefore no alarm will sound if an interruption to flow occurs. There is no display of infusion status. The pump is not suitable for use with medication where delay or under-infusion could result in serious injury.
- Discontinue use of a pump that has been damaged, exposed to severe impact, or which has failed to test properly.
- Discontinue use of a pump that has been submerged in fluid. If any fluid is allowed to enter the pump, other than moisture from cleaning or sanitizing, it should be replaced immediately.
- Do not autoclave the FreedomEdge™. It will melt the plastic and damage the pump.
- Federal law (USA) restricts this device to sale by or on order of a physician.
- Tubing that is pre-primed and shipped at temperatures below freezing could be damaged.

*Generally greater than 2 hours.

FreedomEdge™ Pump Diagram:



Product Listing:

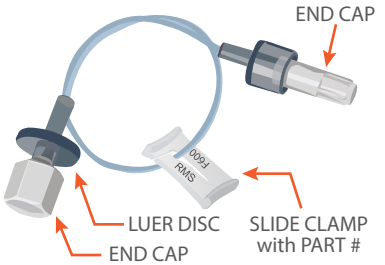
Each FreedomEdge™ Syringe Infusion System includes a carrying pouch and user manual.

Product	Part #
FreedomEdge™ Syringe Infusion Pump	F10020
FreedomEdge™ Carrying Pouch	347400

RMS Precision Flow Rate Tubing™ (case of 50)

Part #	Flow Rate*	Part #	Flow Rate*
F0.5	0.5ml/hr[1]	F60	60ml/hr[2]
F1	1ml/hr[1]	F120	120ml/hr[2]
F2	2ml/hr[1]	F180	180ml/hr[3]
F3	3ml/hr[1]	F275	275ml/hr[3]
F3.8	3.8ml/hr[1]	F420	420ml/hr[3]
F5	5ml/hr[1]	F500	500ml/hr[3]
F8	8ml/hr[1]	F600	600ml/hr[3]
F10	10ml/hr[1]	F900	900ml/hr[3]
F15	15ml/hr[1]	F1200	1200ml/hr[3]
F30	30ml/hr[2]	F2400	2400ml/hr[3]
F45	45ml/hr[2]		

precision FLOW RATE TUBING™



* Flow rates will be approx. 76% of this number with a 30ml syringe.
[1] Sterile water for injection (SWFI) direct flow rates valid with select 20mL syringes.
[2] Adjusted for antibiotic use, for actual flow rates see examples on pages 10-11.
[3] Typically used for viscous drugs, SWFI flow rates will be reduced from stated values.

For Larger Volume Infusions:

The FreedomEdge™ offers all the performance and technology of the FREEDOM60®, in a design for 20ml and 30ml syringes. For larger volumes, the FREEDOM60® accommodates 60ml syringes.

FREEDOM60®
Syringe Infusion System

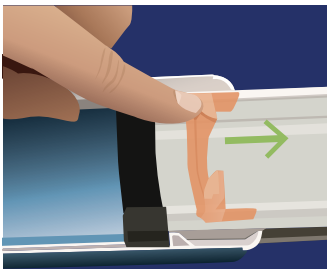
Part #: F10050

Syringes For Use with the FreedomEdge™:

- Becton Dickinson & Co. BD® Luer-Lok™ 20ml (US Reference numbers: 302830 and 301031)
- Becton Dickinson & Co. BD® Luer-Lok™ 30ml (US Reference number: 301033)

Testing the FreedomEdge™ Syringe Infusion Pump:

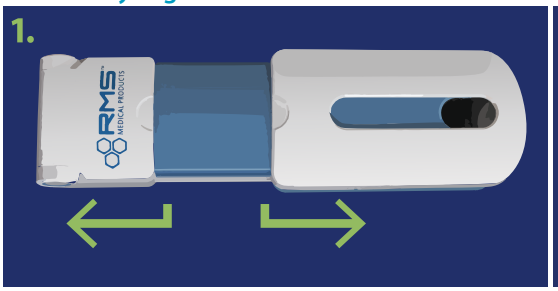
1. Examine the inside to ensure it is free of debris or contamination.
2. Test to make sure the syringe locator moves freely by sliding it up and down with your finger.

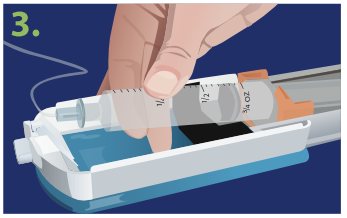


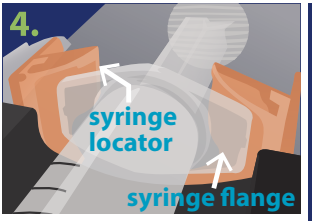
Note: For bench testing of flow accuracy refer to page 10. Note that the negator mechanism which drives the syringe is calibrated for the life of the pump. RMS Precision Flow Rate Tubing™ sets are always measured to flow specification during manufacture and will deliver the appropriate flow rate under controlled conditions.

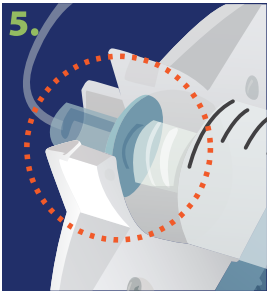
Syringe Loading and Removal Instructions:

To load a syringe:





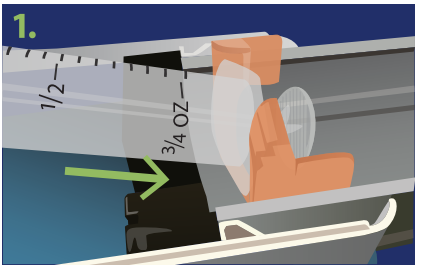


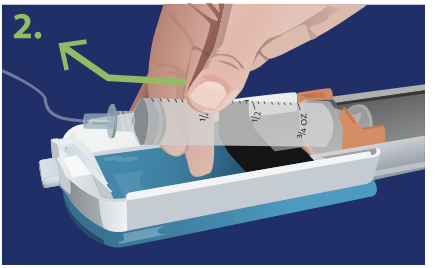


1. Pull firmly to fully extend the pump.
2. Then, open the pump fully by lifting the top cover.
3. With syringe gradations facing up, push the syringe against the syringe locator.
4. Seat the syringe flange into the syringe locator.
5. Seat the luer disc inside the pump nose so that the syringe is firmly attached inside the pump.

Note: You can test proper fit by gently tugging on the syringe. It will stay in place if properly attached.

To remove a syringe:





After the infusion is complete, open the pump.

1. Remove the empty syringe by gently pushing it back to disengage the nose.
2. Lift the syringe up out of the pump.

Note: You will never need to use force to load or remove a syringe.

Selected Flow Rates vs Time:

Note: For assistance in determining which Precision Flow Rate Tubing™ set to use, please contact RMS Medical Products at **800-624-9600**.

Flow Rate vs Time Chart:

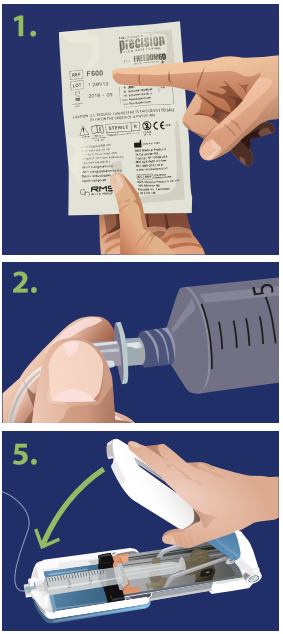
Syringe Volume	1ml/hr	2ml/hr	30ml/hr	45ml/hr	60ml/hr	120ml/hr
5ml	5 hrs.	2 hrs. 30 min.	10 min.	6 min. 42 sec.	5 min.	2 min. 30 sec.
10ml	10 hrs.	5 hrs.	20 min.	13 min. 18 sec.	10 min.	5 min.
15ml	15 hrs.	7 hrs. 30 min.	30 min.	20 min.	15 min.	7 min. 30 sec.
20ml	20 hrs.	10 hrs.	40 min.	26 min. 42 sec.	20 min.	10 min.
25ml	25 hrs.	12 hrs. 30 min.	50 min.	33 min. 18 sec.	25 min.	12 min. 30 sec.
30ml	30 hrs.	15 hrs.	60 min.	40 min.	30 min.	15 min.

Note: Tubing that is pre-primed for and shipped at temperatures below freezing could be damaged.

Starting the Infusion:

1. Verify that you have the correct RMS Precision Flow Rate Tubing™ set.
2. Using sterile technique, remove the cap from the luer disc end of the tubing set and connect the tubing to the pre-filled syringe. *Make sure tubing is appropriately primed, ensuring air has been removed.*
3. Load syringe. Follow syringe loading instructions from **page 6**. Make sure the luer disc is fully seated in the pump's nose.

   Note: You will never need to use force to load or remove a syringe.
4. Remove the cap from the other end of the tubing and connect the tubing to the patient's indwelling needle or catheter.
5. Begin the infusion by closing the pump lid. The infusion begins immediately. *To pause the infusion at any time, fully open the pump.*



Pausing the Infusion:

To stop the flow, fully open the lid to relieve pressure from the syringe plunger. Resume by fully closing the lid again.

Checking Infusion Progress:

Check infusion progress by taking note of the time the infusion started and periodically checking the elapsed time against the movement of the syringe plunger, as seen through the progress window. With 20ml syringes, the approximate rate for antibiotics or other non-viscous solutions can be found on the slide clamp attached to the tubing. (i.e., F60 will flow at 60ml/hr, F30 will flow at 30ml/hr, etc.). 30ml syringes will flow at 76% of the flow rate of 20ml syringes. To correct for this, multiply the 20ml flow rate by .76 for 30ml syringes.

For example: With saline, F120 tubing will flow 120ml/hr with 20ml syringes. After multiplying, the flow rate is 91.2ml/hr with a 30ml syringe.

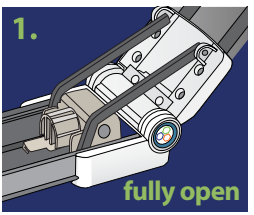
End of Infusion:

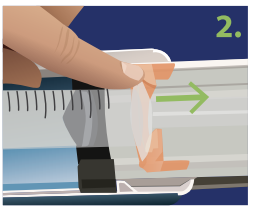
1. Confirm that the syringe is empty.
2. Open the pump by lifting up the top cover.
3. If not attaching another syringe, disconnect the tubing from the patient.
4. Gently remove the syringe as described on page 6.

Note: If the dose is greater than 20ml/30ml and an additional syringe is required, load the additional syringe by repeating section titled, 'Starting the Infusion'.

Troubleshooting:

If the suggestions in this section do not solve your problem, or if problems persist, discontinue use and consult RMS Medical Products and/or your healthcare provider.





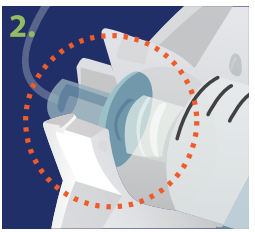
Syringe will not load or remove from pump

Note: You will never need to use force to load or remove a syringe.

1. Make sure the is pump fully open, and that nothing is blocking the syringe locator.
2. Confirm you are not filling the syringe to more than 30ml, or using a syringe larger than 30ml.
3. If you still have difficulty, use one hand to slide the syringe locator all the way back, then place the syringe.

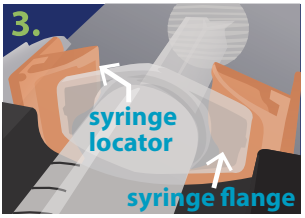
Syringe will not stay inside in the pump

1. Make sure you are using the RMS Precision Flow Rate Tubing™ sets with the luer disc and the RMS tag.
2. Make sure the luer disc end of the tubing has been connected to an approved syringe and that the disc is seated properly inside the nose of the pump.
3. Make sure the flange shape of the syringe is correctly seated into the shape of the syringe locator.



Syringe will not stay inside in the pump (continued)

3. Make sure the flange shape of the syringe is correctly seated into the shape of the syringe locator.



No flow

- Open and close the lid to ensure the syringe pusher slides freely and does not bind.
- Make sure the slide clamp is unclamped and has not been used for an extensive period of time. If the slide clamp is overused it can damage the tubing.
- Test the tubing: Use sterile procedures to disconnect where the indwelling needle or catheter is connected to the rate controlled tubing set; check for medication drip. If medication does not drip, replace the tubing as it may be blocked or damaged. If medication does drip from the Precision Flow Rate Tubing™, then it is most likely a problem with the indwelling needle, catheter, or any fluid path accessories such as a clave connector or needle-free adapter.

Slow flow

- Verify that you are using the proper tubing.
- Verify that you are using the proper syringe. 30ml syringes will flow approx 76% of the rate of a 20ml syringe (e.g. 120ml/hr tubing will flow at approx. 91.2ml/hr).
- If a slide clamp is used for an extensive period of time, it can damage the tubing and affect the flow rate. Try using another tubing set and measure the flow. For 60ml/hr tubing, the syringe plunger should move 10ml in 10 minutes (1ml/min). For 120ml/hr tubing, the plunger should move 10ml in 5 minutes (2ml/min).

Stopping the flow quickly

- The pump is designed to maintain pressure during and after the infusion to prevent blood/drug backflow.
- To stop the flow, fully open the lid to relieve pressure from the syringe plunger.
- You can also use the slide clamp. Only use the slide clamp in the case of an emergency, or when necessary to immediately stop the flow. Overuse can damage the tubing.

Care and Maintenance:

The FreedomEdge™ does not require any preventative maintenance. The FreedomEdge™ with RMS Precision Flow Rate Tubing™ works as a system, which means the tubing determines the flow rate, not the pump; therefore your pump needs no calibration. Selecting the appropriate tubing set for the application ensures the proper flow rate will be achieved. During manufacture, Precision Flow Rate Tubing™ sets are thoroughly quality-tested to high standards, to guarantee flow rate accuracy and appropriate flow rate delivery under controlled conditions.

Cleaning

Clean only those areas that are exposed and external. No attempt should be made to clean any part of the pump that is not easily accessible.

Wipe the outside surface with warm water and detergent or use any surface disinfectant compatible with acetyl-butyl-styrene (ABS) plastic, such as hydrogen peroxide. Avoid the use of alcohol or alcohol-containing compounds, as these tend to make ABS plastic brittle. Wipe again with clean water to rinse.

If necessary, you may clean the inside of the pump with a damp cloth and any cleaning agent compatible with ABS plastic.

Storage:

The FreedomEdge™ syringe infusion pump is recommended to be stored in a cool, dry place. Packaged tubing sets should be stored at room temperature (approximately 16-30°C or 61-86°F).

Testing Flow Accuracy (if required by your local protocol):

1. Completely fill a new BD® 20ml syringe with sterile water. Do NOT use a 30ml syringe for this test.
2. Remove all air from the syringe.
3. Attach a sterile Precision Flow Rate Tubing™ set to the syringe.
4. Remove all air from the tubing set.
5. Load the syringe into the pump and close the lid fully.
6. Monitor the syringe readings and elapsed time to derive an approximate flow rate.
7. Compare your test results to the range of test rates listed in the table below:

Labeled Flow Rate	Bench-Rated Flow Rate	Test Range
F60 (60ml/hr)	72ml/hr	60-84ml/hr
F120 (120ml/hr)	134ml/hr	115-153ml/hr

7a. Bench-Rated Flow Rate: The FreedomEdge™ syringe infusion pump design accounts for the effects of standard clinical conditions on flow rate performance. Under bench test conditions, a 60ml/hr labeled tubing set is designed to generate a nominal infusion rate of 72ml/hr. A 120ml/hr labeled tubing set will generate a nominal bench test rate of 134ml/hr. The FreedomEdge™ generates nominal bench test rates higher than the labeled rate accounting for the following standardized application criteria that affects actual delivery rates under normal clinical circumstances.

	F60 (60ml/hr) Tubing	F120 (120ml/hr) Tubing
Bench Test Rate	72ml/hr	134ml/hr
Less Clinical Effects		
Catheter Gauge (20G PICC)	-7ml/hr	-8ml/hr
Fluid Viscosity	-2ml/hr	-3ml/hr
Venous Pressure	-3ml/hr	-3ml/hr
Label Flow Rate	60ml/hr	120ml/hr

7b. Test Range: To assure consistent test results, keep pump and tubing at the same approximate horizontal plane and monitor flow until syringe empties (approximately 9 minutes for F120 or 18 minutes for F60). The FreedomEdge™ system is factory rated to deliver infusions under strict test conditions over a large number of pumps tested within 7% of nominal with a 95% statistical confidence interval. Under varying bench test and fluid conditions this range can be expected to vary approximately 15% of nominal. For more accurate monitoring, use a stopwatch and finely graduated burette. FreedomEdge™ pump testing is based on ANSI/AAMI National Standard, ID 26-1992, Infusion Devices, August 24, 1992.

If test results in the range indicated cannot be approximated under bench testing conditions, contact RMS Medical Products at 1-800-624-9600.

References:

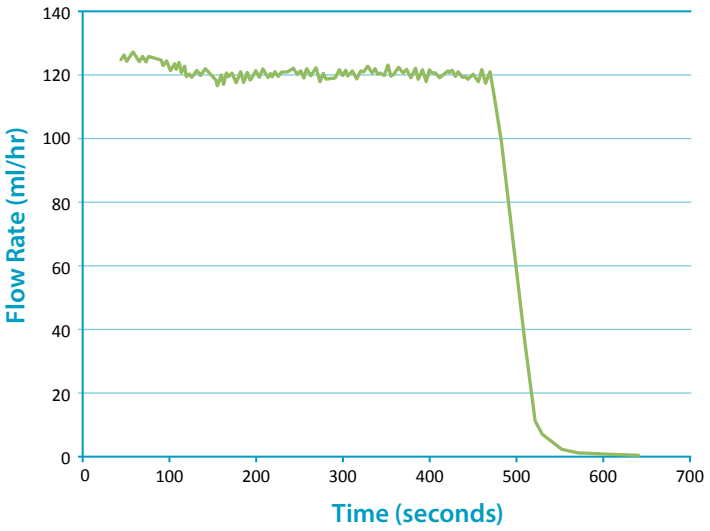
1. Stuhmeier, Mainzer B. MD; Aspects of pressure build-up in the use of electronic infusion devices. II. Need for a pressure limit. Anasth Intensivther Notfallmed (1987 Aug.) 22(4): 185-190.
2. Anasth Intensivther Notfallmed (1987 Aug.) 22(4): 181-184. ANSI/AAMI National Standard, ID 26-1992, Infusion Devices, August 24, 1992.

FreedomEdge™ Flow Profile:

The FreedomEdge™ flow profile shows that the flow rate is consistent throughout the delivery of medication.

FreedomEdge™ Flow Rate vs. Time

Fluid: H_20 · Fluid Volume: 20ml · Tubing Measured: F60, nominal 72ml/hr



Technical Specifications:

System

Reservoir volume:	20ml / 30ml
Residual volume:	<0.4ml
Flow rate accuracy:	± 7%*
Operating pressure: (20ml reservoir)	15psi (peak) 13.5psi (nominal)
Height sensitivity:	± 3% per 12" (30cm)

* Flow rate data recorded at 21°C using 20ml of 0.9% NS. An overall accuracy of ±7% is expected at these values. At higher temperatures, which results in a decrease in viscosity, a higher flow rate is anticipated to occur. The flow rate variation due to changes in temperature is approximately linear and would vary from -20% at 14°C to +20% at 30°C. Fluids considerably more viscous than 0.9% NS are expected to slow the flow rate and consequently may result in longer infusion times. More viscous fluids may be tested before patient use by following the bench test procedures described in this manual.

Pump

Weight:	12oz (0.34kg)
Length:	Closed: 9" (229mm) Extended: 11.75" (299mm)
Width:	3.25" (83mm)
Height:	1.5" (38mm)

Flow Rate Tubing

Length: 6" to 72" (152mm-1829mm)

Flow Rate Tubing / Residual Volume (ml)

F0.5	0.09
F1	0.08
F2	0.10
F3	0.09
F3.8	0.09
F5	0.08
F8	0.08
F10	0.14
F15	0.11
F30	0.13
F45	0.11

F60	0.14
F120	0.16
F180	0.13
F275	0.11
F420	0.10
F500	0.09
F600	0.09
F900	0.08
F1200	0.13
F2400	0.15

precision
FLOW RATE TUBING™

Warranty Information:

Limited Warranty:

RMS Medical Products/Repro Med Systems, Inc. ("Manufacturer") warrants the FreedomEdge™syringe infusion pump to be free from defects in materials and workmanship under normal use. Warranty is limited to Original Purchaser and covers the FreedomEdge™ for a period of two years from the purchase date. This warranty is not valid for any damage caused by the use of non-RMS products. The "Original Purchaser" is the person purchasing the infusion pump from the Manufacturer or Manufacturer's Representative. Warranty does not extend to subsequent purchasers. Subject to the conditions of and upon compliance with the procedures set forth in this limited warranty, the Manufacturer will repair or replace, at its option, any infusion pump, or part thereof, which has been actually received by the Manufacturer or Manufacturer's Representative within the two-year warranty period, and which examination discloses, to the Manufacturer's satisfaction, that the product is defective. Replacement product and parts are warranted only for the remaining portion of the original two-year warranty period.

RMS rigorously tests the FreedomEdge™ using RMS accessories to ensure that the FreedomEdge™ operates in accordance with published specification standards. If non-RMS accessories are used in conjunction with the FreedomEdge™, RMS does not represent that the FreedomEdge™ will operate in accordance with published specification standards. The FreedomEdge™ warranty does not cover third-party products or accessories.

The following conditions, procedures, and limitations apply to the Manufacturer's obligations under this warranty:

- **Parties Covered by this Warranty:** This warranty extends only to the Original Purchaser of the infusion pump. This warranty does not extend to subsequent purchasers.
- **Warranty Performance Procedure:** Notice of the defect must be made in writing to Customer Support Department, RMS Medical Products/Repro-Med Systems, Inc., 24 Carpenter Road, Chester, NY 10918, USA. Notice to RMS Medical Products/Repro-Med Systems, Inc. must include the model and serial number, date of purchase, and description of the defect in sufficient detail to facilitate repairs. Authorization must be obtained by the Original Purchaser from the Manufacturer or Manufacturer's Representative prior to returning the product to the Manufacturer. The defective pump must be properly packaged and returned to the Manufacturer, postage-prepaid. Any loss or damage during shipment is at the risk of the Original Purchaser.
- **Conditions of Warranty:** This warranty does not apply to any product, or part thereof, which has been repaired or altered outside of the Manufacturer's facility in a way so as, in Manufacturer's judgment, to affect its stability or reliability, or which has been subjected to misuse, negligence or accident.

- **Limitations and Exclusions:** Repair or replacement of an infusion pump or component part is the EXCLUSIVE remedy offered by the Manufacturer. The following exclusions and limitations shall apply:
    - No agent, representative, or employee of the Manufacturer has authority to bind the Manufacturer to any representation or warranty, expressed or implied, or to change this limited warranty in any way.
    - THIS LIMITED WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. THERE ARE NO WARRANTIES THAT EXTEND BEYOND THE DESCRIPTION ON THE FACE HEREOF.
    - Manufacturer's liability under this Limited Warranty Agreement shall not extend to special, indirect, or consequential damages.
    - The infusion pump can only be used under the supervision of medical personnel whose skill and judgment determine the suitability of the infusion pump for a particular medical treatment.
    - All recommendations, information, and descriptive literature supplied by the Manufacturer or its agents are believed to be accurate and reliable, but do not constitute warranties.

This warranty and the rights and obligations hereunder, shall be construed under and governed by the laws of the State of New York, USA.

Definition of symbols:

	Caution	QTY	Quantity
	Consult instructions for use	REF	Catalog number
EC REP	Authorized representative in the European Community		Do not reuse
	Use by YYYY-MM-DD or YYYY-MM	SN	Serial number
LOT	Batch code	STERILE R	Sterilized using irradiation
	Manufacturer		

RMS™
MEDICAL PRODUCTS

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